

115TH CONGRESS
2D SESSION

S. 3282

To amend the Controlled Substances Act to require that orders subject to review be submitted through a clearinghouse, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 26, 2018

Mr. GARDNER (for himself and Mr. COONS) introduced the following bill;
which was read twice and referred to the Committee on the Judiciary

A BILL

To amend the Controlled Substances Act to require that orders subject to review be submitted through a clearinghouse, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “DEA Order Clearing-
5 house Act of 2018”.

6 **SEC. 2. REQUIRED CLEARINGHOUSE FOR REGISTRANT OR-**
7 **DERS.**

8 (a) IN GENERAL.—The Controlled Substances Act
9 (21 U.S.C. 801 et seq.) is amended—

1 (1) in section 303(f), in the matter preceding
2 paragraph (1), by striking “The Attorney General”
3 and inserting “Subject to section 303A, the Attorney
4 General”; and

5 (2) by inserting after section 303 the following:

6 **“SEC. 303A. REQUIRED CLEARINGHOUSE FOR REGISTRANT**
7 **ORDERS.**

8 “(a) IN GENERAL.—Not later than 2 years after the
9 date of enactment of this section, the Attorney General
10 shall—

11 “(1) establish a clearinghouse that would sub-
12 ject all orders of controlled substances and listed
13 chemicals to the clearinghouse for recording and re-
14 view, prior to final review by the registrant;

15 “(2) amend the regulations relative to con-
16 trolled substances in schedule II ordering require-
17 ments that would allow for uniform electronic order-
18 ing of controlled substances in schedule II, III, IV
19 and V electronically to the clearinghouse; and

20 “(3) may deny, suspend, or revoke a registra-
21 tion issued under section 303(f), or the registration
22 of a distributor under section 303(b) or 303(e), if
23 the practitioner or distributor, as applicable, is not
24 substantially in compliance with the requirements of
25 this section.

1 “(b) CLEARINGHOUSE.—

2 “(1) IN GENERAL.—An order for a controlled
3 substance may not be filled by the registrant un-
4 less—

5 “(A) the order is first transmitted elec-
6 tronically to the Attorney General, acting
7 through the Administrator of the Drug En-
8 forcement Administration (referred to in this
9 section as the ‘Administrator’);

10 “(B) the Administrator uses the algorithm
11 described in paragraph (2) to determine if the
12 order is an outlier and is potentially suspicious;

13 “(C) the Administrator relays the order to
14 the registrant with whom the order is placed,
15 regardless of whether the algorithm was exceed-
16 ed, for further analysis of the order under sec-
17 tion 1301.74(b) of title 21, Code of Federal
18 Regulations; and

19 “(D) the registrant has received a waiver
20 from the Administrator exempting the reg-
21 istrant from this section.

22 “(2) ALGORITHM.—

23 “(A) IN GENERAL.—The clearinghouse es-
24 tablished under this section shall use an input-
25 based algorithm, including techniques such as

1 artificial intelligence, machine learning, and
2 other methods of analyzing large data, that—

3 “(i) automatically identifies orders
4 that exceed the metrics of the algorithm;

5 “(ii) notifies the registrant if the
6 order is an outlier and is potentially sus-
7 picious;

8 “(iii) is informed by all data available
9 to the Administrator and uses pharmacy
10 best practices;

11 “(iv) takes into consideration existing
12 State and Federal law; and

13 “(v) establishes different parameters
14 for different registrants using relevant in-
15 formation based on pharmacy type, loca-
16 tion, and size.

17 “(B) REFINEMENT.—The Administrator of
18 the Drug Enforcement Administration (referred
19 to in this section as the ‘Administrator’) shall
20 review, update, and revise the algorithm bian-
21 nually based on feedback from industry and rel-
22 evant stakeholders to ensure functionality.

23 “(3) CONSULTATION.—The Administrator shall
24 consult with the Director of the National Institute of

1 Standards and Technology for technical assistance
2 in establishing the clearinghouse.

3 “(c) RESPONSIBILITIES OF DISTRIBUTORS AND MAN-
4 UFACTURERS REGARDING SUSPICIOUS ORDERS.—This
5 section may not be construed as relieving any distributor
6 or manufacturer from the requirements established in sec-
7 tion 1301.74(b) of title 21, Code of Federal Regulations,
8 or any successor regulation, with respect to suspicious or-
9 ders.

10 “(d) CONTRACTOR REGARDING DATA ANALYTICS.—

11 “(1) IN GENERAL.—The Administrator shall
12 award a contract to a public or private entity ena-
13 bling the Administrator to carry out the techno-
14 logical aspects of tracking, processing and evaluating
15 orders under this section.

16 “(2) ELIGIBLE ENTITIES.—An entity is eligible
17 for an award under paragraph (1) if the entity has
18 significant experience in data analytics and in proc-
19 essing the volume of electronic data involved in re-
20 viewing orders under this section within the time-
21 frame required in subsection (c).

22 “(3) CAPABILITIES.—A contract awarded under
23 paragraph (1) shall—

24 “(A) provide a data management and
25 configurable visual analytics solution capable of

1 ingesting and managing data entities, including
2 manufacturers, and distributors, retail dis-
3 pensers across relevant data maintained by the
4 Administrator;

5 “(B) standardize the data format, with the
6 ability to flexibly model data for analyses and
7 link data across sources; and

8 “(C) provide an environment for analysis
9 that is interoperable.

10 “(4) COMMERCIAL ITEMS.—The Administrator
11 shall comply with section 3307 of title 41, United
12 States Code, in awarding a contract under para-
13 graph (1). The Administrator may not enter into a
14 contract for any capabilities sought under paragraph
15 (1) that are not for commercial items unless the Ad-
16 ministrator first determines in writing that no com-
17 mercial items are suitable to meet the needs of the
18 Drug Enforcement Administration.

19 “(5) TIMELINE OF CONTRACT.—Any contract
20 awarded under paragraph (1) for a data manage-
21 ment and visual analytics solution shall require the
22 public or private entity awarded such contract to de-
23 liver a functioning solution sufficient to fulfill the
24 purposes of this section not later than 180 days
25 after the date on which the contract is awarded, un-

1 less the Administrator grants an extension for un-
2 foreseen delays.

3 “(6) FEDERAL ACQUISITION REGULATION.—A
4 contract awarded under this subsection shall be in
5 accordance with the Federal Acquisition Regulation.

6 “(7) ACCESS TO DATA.—An entity that is
7 awarded a contract under this subsection shall have
8 access to the relevant data to create the system.

9 “(e) WAIVER.—

10 “(1) IN GENERAL.—Beginning on the date on
11 which the 36-month period described in subsection
12 (b)(1)(A)(ii) expires, a pharmacy may submit to the
13 Administrator an application for a waiver from the
14 requirements of subsection (b)(1)(A) if the phar-
15 macy is unable to transmit orders electronically.

16 “(2) RESPONSE.—The Administrator shall ap-
17 prove or deny an application submitted under para-
18 graph (1) not later than the 90-day period beginning
19 on the date on which the application is received.

20 “(3) LIABILITY.—No waiver issued under para-
21 graph (1) shall mitigate the liability of the pharmacy
22 for any drugs diverted that did not pass through the
23 clearinghouse.

24 “(f) FUNDING.—

1 “(1) DIVERSION CONTROL FEE ACCOUNT.—The
2 activities performed under this section shall be con-
3 sidered to be elements of the diversion control pro-
4 gram for purposes of section.

5 “(2) PROHIBITION.—No registrant may pass on
6 the cost of the clearinghouse to its customers.”.

7 (b) TECHNICAL AND CONFORMING AMENDMENT.—
8 The table of contents for the Controlled Substances Act
9 (21 U.S.C. 801 et seq.) is amended by inserting after the
10 item relating to section 303 the following:

“Sec. 303A. Required clearinghouse for registrant orders.”.

○